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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/553,339	10/26/2006	Neil P. Desai	638772000301	3605

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EXAMINER	
TSAY, MARSHA M	
ART UNIT	**PAPER NUMBER**
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/553,339	DESAI ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-25* is/are pending in the application.

4a) Of the above claim(s) *7-9 and 14-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6,10-13,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/27/09*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: .

This Office action is in response to Applicants' remarks received October 27, 2009.

Applicants' arguments filed have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claim 1 is canceled. Claims 7-9, 14-23 are withdrawn. Claims 2-6, 10-13, 24-25 are currently under examination.

Priority: The request for priority to provisional application 60/432317, filed December 9, 2002, is acknowledged.

Objections and Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-6, 10-13, 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Damascelli et al. (2001 Cancer 92(10): 2592-2602; previously cited) in view of Desai et al. (US 6537579; IDS 02.20.08) as evidenced by Ibrahim et al. (2000 Proc Am Soc Clin Oncol 19: abstract 609F). The Ibrahim et al. reference is cited as evidence to note that ABI-007 is cremophor-free.

Damascelli et al. disclose ABI-007, a paclitaxel-human albumin nanoparticle having a dimension of 150-200 nm (p. 2593 col. 2, Fig. 1). It is known that ABI-007 is cremophor-free

(evidenced by Ibrahim et al.). Damascelli et al. do not disclose a weight ratio of albumin to paclitaxel is about 1:1 to about 9:1.

Desai et al. disclose dosage forms of ABI-007 contain 30 mg, 100 mg, or 300 mg of paclitaxel in a vial (col. 14 lines 4-5). Desai et al. further disclose that unit vessels of ABI-007 may contain between 1 mg to 1000 mg of active drug (col. 15 lines 39-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Damascelli et al. by determining the optimum weight ratio of albumin to paclitaxel, i.e. 9:1, as suggested by Desai et al. which will result in a composition that will deliver paclitaxel most effectively in an albumin delivery system (claims 2-6, 10-13, 25). The motivation to do so is given by Desai et al., which disclose a weight ratio of albumin to paclitaxel of 9:1. Since Desai et al. disclose ABI-007 can contain up to 1000 mg of active drug and further disclose that ABI-007 can contain 100 mg of paclitaxel, it would be reasonable for one of ordinary skill to note that a 1000 mg vial of ABI-007 would contain 100 mg paclitaxel and 900 mg albumin, i.e. a weight ratio of 9:1 of albumin to paclitaxel.

Regarding the ratio of 5:1 (albumin to paclitaxel) recited in claim 24, it should be noted that generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum

combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler,* 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). In this instance, since Desai et al. disclose the weight ratio of 9:1 (albumin to paclitaxel), it would be reasonable for one of ordinary skill to want to further determine which other weight ratios would optimize delivery of paclitaxel.

In view of Applicants' amendments and remarks, the Desai et al. reference has been added to the 103(a) rejection.

Therefore, the claims remain rejected under 103(a) for the reasons noted above.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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